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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/776, 350      04/18/97      MACLEAN

A      117-231

EXAMINER	
LINGAR, S	
ART UNIT	PAPER NUMBER

HM12/0922

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DATE MAILED:09/22/00  
*23***Please find below and/or attached an Office communication concerning this application or proceeding.****Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>08/776,350</b>	Applicant(s) <b>Maclean et al</b>
	Examiner <b>Ungar</b>	Group Art Unit <b>1642</b>

Responsive to communication(s) filed on Jul 3, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 43-58 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 43-58 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The Amendment filed July 3, 2000 (Paper No. 22) in response to the Office Action of March 1, 2000 (Paper No. 21) is acknowledged and has been entered. Claims 43-58 are currently pending and are being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following objections are being maintained.

The objection to the specification recited in Paper No. 21, Section 4, page 2 is maintained.

Applicant argues that amendment of the specification to recite US Patent No. 6,040,169 overcomes the rejection because the subject matter is now properly incorporated by reference, pursuant to MPEP 608.01(p). The argument has been considered but has not been found persuasive because MPEP 6.08.01(p) specifically states that:

“Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky , 474 F.2d 671, 177 USPQ 144, (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. “

MPEP 6.08.01(p) further states that:

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"Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re Hawkins , 486 F. 2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins , 486 F. 2d 579, 179 USPQ 163 (CCPA 1973); In re Hawkins , 486 F. 2d 577, 179 USPQ 167 (CCPA 1973)."

Applicant's arguments are not persuasive and the objection is maintained.

4. The following rejections are being maintained:

***Claim Rejections - 35 USC § 112***

5. Claims 43-50 and 52-57 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 21, Section 5, pages 2-4.

Applicant argues (a) as drawn to the nonpersuasive DeGeorge v. Bernier, that when citing case law the principles of patentability are the same irrespective of the technical field, (b) the scope and the meaning of the claims must be interpreted in light of the specification and the specification teaches as follows that is that (1) claim 43 states that "a mutant HSV type I that has a non-functional gamma 34.5 gene in the long repeat, (2) Deletion of gamma 34.5 results in variants that grow as well as wt virus, (3) provides information on a mutant known in the art that contains a 1000 bp deletion in gamma 34.5 and provides details as to the production of another known mutant virus that has a 759 deletion in gamma 34.5, (4) the summary of the invention states the use of a mutant HSV which has been modified in the gamma 34.5 gene of the long repeat region such that the gene is non-function, (5)

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non-functional is defined, (c) claim 43 claims a method using a specific class of HSV-1 mutants and the specific class of mutants is not claimed, contrary to Examiner's statement on page 4, line 5 of Paper No. 21, and a specific working example has been provided (d) established case law agrees that claims are enabled if any of the following conditions are met, that is that the specification must provide direction, guidance and working examples, the methods needed to practice the invention are well known and there was a high level of skill in the art at the time the application was filed. Applicant argues that (d1) the specification teaches a specific class of gamma 34.5 mutants, (d2) all of the methods required to produce the mutants are detailed in the specification or cross-referenced and there was a high level of skill in the art at the time the invention was made.

The arguments have been considered but have not been found persuasive because (a') the applicability of case law is dependent upon the fact pattern of the two cases. It is clear that the fact pattern drawn to a data processing system printer and an in vivo cancer treatment are not the same. The fact pattern in DeGeorge v. Bernier is not relevant to the instant fact pattern, (b') Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, Applicant is reminded that the claims define the subject matter of his invention and it is clear, that the claims as broadly written are intended to cover a whole universe of mutants, (c') the claims were rejected under 35 USC 112, first paragraph for not teaching how to make and use the method using the broadly claimed mutants, the specific working example is not sufficient enablement for the

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broadly written claims for the reasons previously set forth, (d1') applicant is arguing limitations not recited in the claims as presently constituted, (d2') Applicant has not provided any general guiding principles upon which the invention is based to enable the scope of the invention for the reasons previously set forth.

6. Claims 51 and 58 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 21, Section 7, pages 6-8.

Applicants argue that the rejection is obviated by the attached Deposit Receipt and the following comment that any and all restrictions imposed by the depositor on public availability of the deposited material will be irrevocably removed. The argument has been considered but has not been found persuasive because review of the response in the file did not reveal either a deposit or a comment referring to mutant 1716. Further, the specification has not been amended to recite the date of deposit or the complete name and address of the depository. Applicant is reminded that a deposit declaration must include the statement that the deposit will be replaced if viable samples cannot be dispensed by the depository

***Claim Rejections - 35 USC § 103***

7. Claims 43-58 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 21, Section 8, pages 8-10.

Applicant argues that (a) the reference only makes a passing reference to the treatment of melanoma and there is no exemplification of treatment of any type of cancer other than a primary brain tumor and that in order to be obvious the prior art must suggest or motivate modification of the reference or combined teaching, there must be an expectation of success and the prior art must teach or suggest all of the

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limitations, (b') the '096 patent does not show how treating melanoma treatment would be attempted with any reasonable expectation of success and HSV is known to inhabit brain and nervous system, treatment of a secondary tumor which did not originate from the nervous system would not have been considered with any expectation of success, (c) Davey et al discusses treatment of cerebral metastases from malignant melanoma with radiotherapy and not with HSV, (d) the specific mutant of the present invention can be successfully used with advantageous results on secondary tumors which was unknown at the time the invention was made.

The arguments have been considered but have not been found persuasive because (a') all of the teachings of an issued patent are considered enabling, the combined references provide both suggestion and motivation to modify the combined references for the reasons previously set forth, one would have a reasonable expectation of success in treating melanoma since the primary reference specifically suggests the treatment of melanoma and all of the limitations of the claims are taught in the combined references for the reasons previously set forth, (b') the issued patent teaches that the method can be used to treat melanoma, the issued patent is enabling, (c') Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re

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Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981), (d') it would have been *prima facie* obvious to substitute one HSV-1 deletion mutant for the reasons previously set forth..

**New Grounds of Rejection**

***Claim Rejections - 35 USC § 112***

8. If applicant were able to overcome the rejection under 35 USC 112, first paragraph above drawn to lack of enablement of how to make and used the broadly claimed mutant, Claims 43-58 would still be rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 21, Section 6, pages 4-6.

Applicant's arguments drawn to the rejection of claims 43-50 and 52-57 are relevant to the instant rejection.

Applicant argues that the specification provides extensive examples as to the use of the mutant viruses in the treatment of brain tumors and cites exemplification in the specification. The argument has been considered but has not been found persuasive because the only effective method of treatment exemplified is intratumoral administration of mutant 1716.

9. All other objections and rejections recited in Paper No. 21 are withdrawn.

10. No claims allowed.

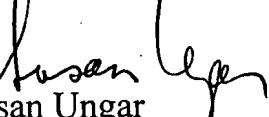
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

  
Susan Ungar  
Primary Patent Examiner  
September 20, 2000